. ATENT COOPERATION TRE. .TY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 30 May 2001 (30.05.01)	
International application No. PCT/CA00/01071	**Applicant's or agent's file reference** UBC135PCT
International filing date (day/month/year) 15 September 2000 (15.09.00)	**Priority date** (day/month/year) 17 September 1999 (17.09.99)
Applicant HODGSON, Antony, J. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

17 April 2001 (17.04.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Nestor Santesso
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

CA0001071

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

INFORMATION CONCERNING ELECTED OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

To:

ROWLEY, Cecil, Alan
P.O. Box 59
51 Riverside Parkway
Frankford, Ontario K0K 2C0
CANADA

Date of mailing (day/month/year) 30 May 2001 (30.05.01)	
Applicant's or agent's file reference UBC135PCT	**IMPORTANT INFORMATION**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/CA00/01071	15 September 2000 (15.09.00)	17 September 1999 (17.09.99)

Applicant
THE UNIVERSITY OF BRITISH COLUMBIA et al

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

   EP :AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE
   National :AU,BG,CA,CN,CZ,DE,IL,JP,KP,KR,MN,NO,NZ,PL,RO,RU,SE,SK,US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

   AP :GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW
   EA :AM,AZ,BY,KG,KZ,MD,RU,TJ,TM
   OA :BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG
   National :AE,AG,AL,AM,AT,AZ,BA,BB,BR,BY,BZ,CH,CR,CU,DK,DM,DZ,EE,ES,FI,GB,
   GD,GE,GH,GM,HR,HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MW,
   MX,MZ,PT,SD,SG,SI,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

3. The applicant is reminded that he must enter the "national phase" **before the expiration of 30 months from the priority date** before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing , if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

   Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

   The entry into the European regional phase is postponed **until 31 months from the priority date** for all States designated for the purposes of obtaining a European patent.

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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence and Administrative Instructions, Section 601(a))

Date of mailing *(day/month/year)*	10.05.01
Applicant's or agent's file reference: UBC135PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA 00/01071	15/09/2000	17/09/1999

Applicant

THE UNIVERSITY OF BRITISH COLUMBIA et al

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

17/04/2001

2. This date of receipt is:

☒ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).

☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(c)).

☐ the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☐ **ATTENTION:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide*, Volume II.

☐ *(If applicable)* This notification confirms the information given by telephone, facsimile transmission or in person on: _____

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

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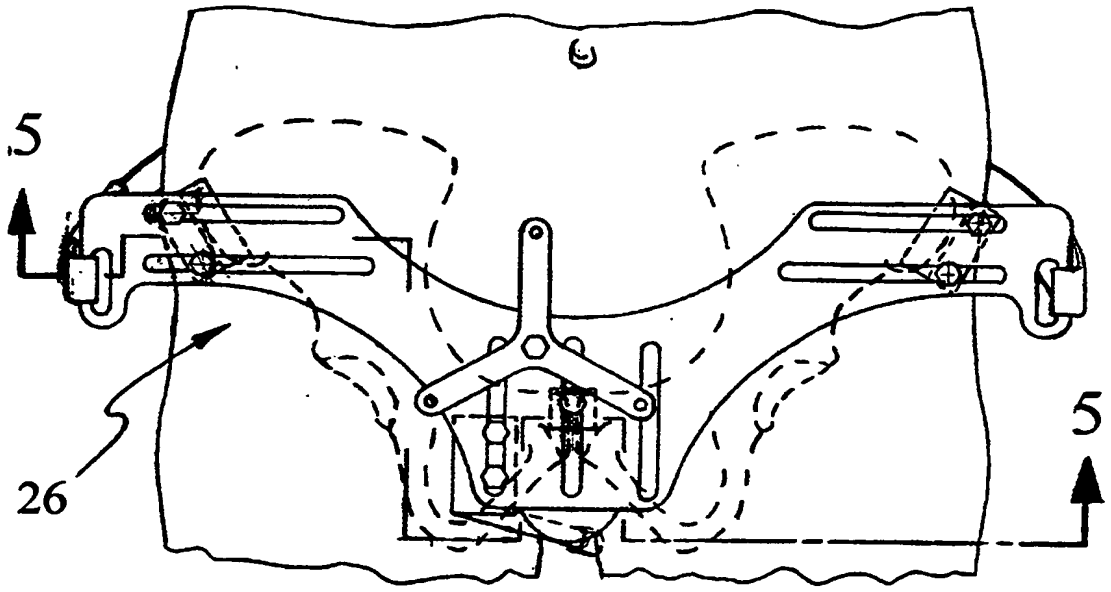
(54) Title: POSITIONING METHOD AND APPARATUS FOR MOUNTING A TRACKER



(57) Abstract: A method for apposing one body to another across a soft tissue interface which minimizes relative movement between the two bodies by using normal constraints to attenuate skin motion artifacts. Apparatuses based on this method consist of a multiplicity of contact surfaces and means for applying seating forces; and may include adjustment mechanisms for accommodating a range of body sizes and if desired sensing means to permit compensating for small relative motions and monitoring correct performance of the system may be provided.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Positioning Method and Apparatus for Mounting A Tracker

FIELD OF THE INVENTION

This invention pertains to a method and apparatus for securing one body to another across a soft tissue interface so as to minimize their relative movement, for example, as is required in biomechanical studies and calibrated surgical interventions.

Background to the Present Invention

In the field of biomechanics, it is often desired to track the position of a bony structure (such as, for example, the pelvis during a gait assessment). The most accurate technique currently known requires that one or more objects be inserted into the bone and subsequently tracked. Two examples of this technique are: (1) roentgen stereophotogrammetry (RSA), in which metal spheres (typically made of tantalum) are inserted into a bone, their locations identified on two substantially perpendicular X-ray images, and their three dimensional positions reconstructed using a mathematical algorithm (Kiss J, Murray DW, Turner-Smith AR, Bulstrode CJ. Roentgen stereophotogrammetric analysis for assessing migration of total hip replacement femoral components, Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine.v 209 n 3 1995, p 169-175.) and (2) optical tracking, in which a bone pin is inserted transcutaneously, a marker array mounted to an extension of the bone pin, and an optical measurement device used to identify the location of the marker array (Cinquin P, Lavallee S, Leitner F, Minfelde R, Picard F, Saragaglia D, Schultz, H-J. WO9840037A1: Process and device for the preoperative determination of positioning data of endoprosthesis parts. Issued: Sept. 17, 1998).

Marker arrays are typically constructed of either retroreflective markers or of active light-emitting diodes. Non-optical tracking systems such as ultrasonic or magnetic systems may also be used in conjunction with bone pins to track the bone. Since this technique is invasive, it is undesireable for all but the most critical applications and in more routine applications, less invasive techniques are used. For example, it is common in gait laboratories to attach optical marker arrays to a subject using elasticized bands wrapped around relevant limb segments. Alternatively, retroreflective tape may be applied directly to a subject's skin. Unfortunately, since skin can move relative to the underlying bone, any marker mounted to the skin will also move relative to the bone, which introduces inaccuracies into the measurement (Stacoff A, Nigg BM, Reinschmidt C, van den Bogert AJ,

Lundberg A. Tibiocalcaneal kinematics of barefoot versus shod running. J Biomech. 2000 Nov 1;33(11):1387-1395).

Similarily, in the field of surgery, it is often desired to accurately track the location of a bony structure in order to perform a surgical task at a desired location. Examples include taking a tissue biopsy, inserting a pedicle screw or ablating neural tissue. In many of these situations, a preoperative scan is made to identify the target for the surgery and the task for the surgeon is to identify this location in the operating room. A common approach is to secure a frame to the patient prior to the preoperative scan (e.g., a stereotactic frame for neurosurgery), leave it intact between taking the scan and performing the surgery, and using it as a reference frame during the surgery to identify the target location. In many of these procedures, high accuracy is desired (on the order of less than a millimetre), so transcutaneous bone pins are used to provide mounting points for the frame.

In addition to requiring an additional preoperative surgical procedure, the requirement that the frame remain in place between the scan and the procedure has typically meant that the scan must be performed the morning of the procedure, thus delaying the surgical procedure and rendering the patient quite uncomfortable in the interim. A remountable frame has been developed which partially addresses this need, but it requires a series of X-ray scans to verify the accuracy of the reattachment (US#5601569: Stereotactic frame and localization method. Inventor(s): Pisharodi; Madhavan , Issued: Feb. 11, 1997).

As another example of a surgical need for accurate localization of bony structures, in total knee arthroplasty a surgeon needs to identify the anatomical planes of the femur and tibia in order to prepare the bone surfaces to receive the implant. Accuracy of alignment is a significant concern, and computer-assisted procedures have recently been developed. In these procedures, it is important to identify the location of the hip centre. The most accurate technique to date requires the insertion of a bone pin on the pelvis (Cinquin WO9840037A1), but this is considered undesireable. Others have tried to use externally mounted markers to track the hip (Leardini A, Cappozzo A, Catani F, Toksvig-Larsen S, Petitto A, Sforza V, Cassanelli G, Giannini S. Validation of a functional method for the estimation of hip joint centre location. J Biomech. 1999 Jan;32(1):99-103). Such markers have been attached to a close-fitting padded brace which is secured about the patient's abdomen and pelvis and the brace is assumed to move comparatively little relative to the

pelvis, although studies have shown that the relative movement is markedly greater than that of bone pins, so there is significant room for improvement.

Another group has performed computer-assisted knee surgery by holding the pelvis still during hip centre location, but this approach lacks robustness and could lead to large errors (Krackow KA, Bayers-Thering M, Phillips MJ, Bayers-Thering M, Mihalko WM. A new technique for determining proper mechanical axis alignment during total knee arthroplasty: progress toward computer-assisted TKA. Orthopedics. 1999 Jul;22(7):698-702).

In all of these applications, there is a need for a device which can be mounted external to the body yet follow the motions of the underlying bony structure without significant deviations such as currently arise due to relative skin motion. Ideally, such a device should be able to be removed and remounted with high repeatability in positioning relative to the underlying bone.

It is well known in the field of machining fixture design that two objects may be fully constrained relative to one another by imposing six constraints between them (two objects without constraints between them are said to have six degrees of freedom relative to one another, and each constraint applied removes one degree of freedom of relative movement) (Blanding DL, "Exact Constraint", ASME Press, 1999). Such connections are known as kinematic couplings (Hale 2000 – US#6065898 Three tooth kinematic coupling. Issued: May 23, 2000; Slocum 1997 – US#5683118 Kinematic coupling fluid couplings and method. Issued: Nov. 4, 1997). In theory, a constraint may be created by establishing point contact between two objects, which prevents relative movement along the common normal at the point of contact. In practice, this leads to high stresses so it is common to make each contact point more conforming, which, due to intrinsic elasticity in physical materials, spreads the contact over a small patch. In some applications, friction may act as a constraint to movement, in the sense that finite forces may be applied to an object without causing it to move relative to another, but since frictional forces may act at any position, they do not allow accurate localization of one object relative to another; accurate localization requires strictly normal constraints. In order to properly design a fixture using strictly normal constraints, the six constraints must be arranged so that no line can be drawn which intersects all six normals (two parallel lines are considered to intersect at infinity); if such a line can be drawn, it represents an axis of rotation about which the body is free to move.

BRIEF SUMMARY OF THE INVENTION

It is an object of the invention to provide both a method and apparatus for apposing an external object to a bony structure overlaid by soft tissue in such a manner as to minimize relative movement of the object and bony structure despite the potential for relative movement between the skin and the underlying bony structure.

It is the principal object of Applicants' invention to provide a method for apposing an external body to an underlying bony structure across a soft tissue interface using normal constraints to minimize relative motion and maximize remounting repeatability.

It is a further object of Applicants' invention to provide a means for determining relative movement which may occur between the external object and the underlying bony structure by measuring changes in relative displacement between the bone structure and external object in the direction of the normal in the regions of contact.

Broadly the present invention relates to a device for indicating the position of a rigid body covered with a layer of soft pliable material, comprising: a rigid element, a plurality of contact surfaces mounted on said rigid element, said contact surfaces being arranged in a pattern wherein each said surface is oriented at a different angle to a reference line of said rigid element so that when the surfaces contact the soft material said contact surfaces apply pressure in different directions relative to said reference line and in a direction normal to an underlying portion of said rigid body, thereby to fix said rigid element substantially immobile relative to said rigid body by a reaction force at each of said contact surfaces acting on said rigid body through said layer of soft pliable material, and a seating means of applying a seating force between said rigid element and said rigid body to force said contact surfaces to apply said pressure and maintained said pressure at each said contact surface during use of the device whereby relative motion between said rigid element and said rigid body due to the soft pliable material sliding tangentially over the body is minimised.

Preferably at least one of the contact surfaces is adjustable in position relative to said rigid element to accommodate a range of sizes and shapes of said rigid body.

Preferably a marker array will be fixed to said rigid element.

Preferably a means of measuring the thickness of the said layer of soft material is incorporated into at least one and more preferably each contact surface to enable the user to

correct for any relative motions which may occur, which permits to verify proper attachment of the device, and to monitor any loss of constraint.

Broadly the present invention also relates to a method of indicating the position of a rigid body when said rigid body is covered with a layer of soft material, comprising the steps of arranging six contact surfaces and fixing them to a common rigid frame, applying said rigid frame so that said surfaces contact the soft material and fully constrain said rigid frame relative to said rigid body by a reaction force at each of the contact surfaces, acting through said layer of soft material substantially normal to the surface of said rigid body in the region of contact, and applying a seating force between said rigid frame and said rigid body such that a reaction force is maintained at each contact surface during use.

Brief Description of the Drawings

Fig. 1 (a) shows the frontal aspect of the pelvic region of a typical patient and

Fig 1 (b) shows the frontal aspect of the pelvic region of a typical patient with an embodiment of the invention as adapted for tracking the pelvis ("hip tracker") applied.

Fig. 2 shows the posterior aspect of the patient with the hip tracker applied.

Fig. 3 is an exploded view looking on the posterior aspect of the preferred embodiment of the hip tracker.

Fig. 4 is a view on the frontal plane of a typical person's pelvic region with the preferred embodiment of the hip tracker applied.

Fig. 5 is a modified section view taken on line 4 – 4 of Fig. 4, looking proximally through the pelvic region of the patient with the preferred embodiment of the hip tracker applied.

Fig. 6 shows a frontal view on the patient showing the bony outline of the pelvis, reaction forces with substantial components in the frontal plane, the lines of action of these reaction forces, and their corresponding contact surfaces on the hip tracker.

Fig. 7 shows the head of a typical patient with an embodiment of the invention as adapted for tracking the skull ("head tracker") applied.

Fig. 8 is a view looking crainially and posteriorly, parallel to the bridge of the nose, showing the contact point between the patient and the head tracker at the zygomatic arch and at the bridge of the nose over the nasal bones.

Fig. 9 is a view on the frontal plane of a typical person's pelvic region with an alternate embodiment of the hip tracker applied.

Fig. 10 is a modified section view taken on line 10 – 10 of Fig. 9, looking proximally through the pelvic region of the patient with the alternate embodiment of the hip tracker applied.

Fig. 11 shows a frontal view on the patient showing the bony outline of the pelvis, reaction forces with substantial components in the frontal plane, the lines of action of these reaction forces, and their corresponding contact surfaces on the alternate embodiment of the hip tracker.

Fig. 12 is a schematic illustration of an contact block of the present invention incorporating an ultrasonic sensor.

Descriptions of the Preferred Embodiments

The present invention takes advantage of the fact that the soft tissues overlying bony structures are often comparatively thin and, once loaded, do not compress significantly more over time. Recognizing that soft tissues are typically mobile parallel to the underlying bony surface, a contact face on an external object is therefore effectively unconstrained except in the normal direction. To achieve full constraint between the external object (rigid element) and the underlying bony structure, then, it is necessary to design a set of six contact faces oriented according to the known principles of fixture design (see, for example, Blanding DL, "Exact Constraint", ASME Press, 1999 for details) so as to prevent relative movement of the two bodies through normal contact forces only. In general, since each contact can only sustain compressive forces, means must also be provided for ensuring that each contact is loaded with a bias towards compressive forces to prevent loss of contact and constraint. In general, any system of forces and torques applied to any portion of the above described external object or rigid element can be reduced to a single combination of a force and torque known as a wrench. Once the locations and orientations of the contact elements or blocks (as will be described below), as well as the desired contact forces at each contact element, are specified, the corresponding wrench can be computed using standard methods from theoretical mechanics.

One means of producing a desired wrench is to apply a set of forces (known as seating forces) equal in number to the number of contact points and oriented substantially collinearly with the normals at the points of contact. By this means, each applied force affects the contact force only at the one contact point through which it passes. As it is often inconvenient to apply a force directly through a contact point, one may offset the applied force lateral to its direction of application to a more convenient location and apply a countervailing torque to compensate for the added torque produced by the position shift.

Forces may be applied to the above described rigid element using a variety of means of reacting against a third body. For example, it is common to attach an elastic strap from a desired point on the rigid element to a connection point on a third body such that the elastic strap is oriented substantially along the intended direction of application of the applied force and is stretched when connected. The magnitude and direction of this seating force will therefore be largely insensitive to small motions of the third body relative to the rigid element.

Since the human arm is compliant, similar to an elastic element, it is possible to provide a desired seating force simply by pushing on the rigid element at the desired point of application of the force on the rigid element in substantially the desired direction.

Alternative means of applying the seating force may also be used . For example, one could replace the elastic strap with a rigid strap wrapped around a compliant element on said third body (for example, a rigid strap wrapped around soft tissue overlying a bony structure). Alternatively, a mass could be positioned such that the gravitational force acting on this mass acts through the desired point on the rigid element in the desired direction. Similarily, electromagnetic repulsion fields such as are embodied in a solenoid could be used to generate a force between the rigid element and the said third body along a desired line between the two.

The magnitude of the seating force should be insensitive to small displacements of the the above described rigid element. These forces as above described may be applied through compliant means such as a spring or hand pressure, or other objects which can convert various fields into forces, such as a mass acted on by gravity, a magnet acted upon by a repulsive magnetic field or a solenoid acted upon by an electromagnetic field. Tightened straps may also be used for this purpose if they are themselves sufficiently compliant or if

they are wrapped around a compliant object such as a portion of the subject's body covered with a sufficient amount of soft tissue as is taught hereinbelow.

Once a system has been designed for a particular anatomical structure (e.g., the skull, jaw, scapula, pelvis, tibia, calcaneus, etc.), provision may also be made for tracking the external object with a motion measurement system. This will typically entail providing a mounting point for a marker array (e.g., light-emitting diodes for an optoelectronic system, tantalum balls for an RSA system, a receiving coil for a magnetic localizer, etc.).

Description of the Preferred Embodiment of the Invention as Adapted for Tracking the Pelvis ('Hip Tracker')

The embodiment illustrated is not intended to be exhaustive of limit the invention to the precise form disclosed. It is chosen and described to explain the principles of the invention and its application and practical use, and thereby enable others skilled in the art to utilize the invention.

NOTES AND ABBREVIATIONS:

ASIS Anterior Superior Iliac Spine

PD Proximal-distal

ML Mediolateral

AP Anteroposterior

All materials are rigid metal or plastic unless noted

'Rightward', 'Leftward', 'Right', and 'Left' directions refer to the patient's right or left

Fig. 1 (a) shows the frontal aspect of the pelvic region of a typical patient showing the left anterior superior iliac spine (ASIS) 21, the right ASIS 22, and the pubic tubercle 23, all well known bony landmarks palpable on most patients. **Fig. 1 (b)** shows the patient with the preferred embodiment of the hip tracker 26 applied, contacting the patient at bony landmarks 21, 22, and 23. Also, a portion of the hip tracker 26, pubic arch contact rod 34, extends through the crotch area to contact the patient at the inferior ramus of the right pubis. Waist strap 27 is fastened around the waist under tension and in this embodiment provide means of applying a seating force between said rigid element (tracker structure) and said rigid body (bone in the body of the patient).

Fig. 2 shows the posterior aspect of the patient with the hip tracker 26 applied, showing waist strap 27 fastened under tension around the patent's waist proximal to the posterior superior iliac spines and crotch strap 28 emerging from its attachment to the hip tracker at the posterior end of pubic arch contact rod 34 to join the waist strap 27 at a point to the right of the patient's midline. The lengths of straps 27 and 28 can be adjusted and fixed using buckle/adjuster assemblies 29 and 24 respectively and can also be released and rejoined at buckle/adjuster assemblies 29 and 24 without changing their relaxed lengths. When tightened and joined, the straps 27 and 28 together apply a seating force to the hip tracker 26 oriented posterior, proximal, and towards the patient's right, passing through the area bounded by the contact points between the hip tacker 26 and the patient at the left ASIS, the right ASIS, and the pubic tubercle (see Fig. 1a). This seating force is generated by the elasticity of the soft tissues lying under the strap and by elasticity in the strap itself.

Alternately, straps 27 and 28 may be replaced by network of elastic material of fixed relaxed length or an elastic garment enveloping the posterior aspect of the patient's pelvic region and attached to the hip tracker 26 such that a posterior, proximal, and rightward oriented seating force is applied to the hip tracker 26 relative to the patient. The seating force is sufficient to ensure positive contact at the six contact points described below between the hip tracker 26 and the patient under the disturbing forces expected during phases of the procedure where the hip tracker's 26 position is being recorded, for example during articulation of the femur.

Fig. 3 is an exploded view looking on the posterior aspect of the preferred embodiment of the hip tracker 26. The hip tracker 26 is formed from a rigid element or frame 30 provided with a plurality of mounting slots 100 and 102 including an upper and lower substantially parallel pair of left mounting slots and a corresponding pair of right mounting slots 104 and 106 respectively. The upper slots 100 and 104 are axially aligned as are the lower slots 102 and 106. Also provided in the frame 30 is a set of three parallel slots 108, 110 and 112 that have their axes substantially perpendicular to the axes of the slots 100 and 102. The slot 110 is position substantially on the vertical center line of the frame 30.

Left ASIS contact block 31 is bolted to the hip tracker rigid element 30 or frame 30 via bolts 114 and 116 that pass through the slots 100 and 102 respectively and thread into corresponding threaded holes (not shown) in the block 31. Obviously the position of the block 31 relative to the frame 30 may be adjusted by loosing the bolts 114 and 116 and sliding along the slots 100 and 102. If desired the width of the slots 100 and 102 may be

made wider than the diameters of the bolts 114 and 116 to permit limited angular adjustment of the block 31 relative to the frame 30

Similarly right ASIS contact block 32 is attached to frame 30 via bolts 118 and 120 extending through the slots 104 and 106 respectively. The structure of the connection of the block 32 to the frame 30 is essentially the same as for block 31 and thus will not be described again in detail

A right-left adjustment range of at least 85 mm is provided for each ASIS contact block 31 and 32 to accommodate the greater or 'false' pelvis width (distance between the right and left ASIS) of most patients.

Block 31 has substantially perpendicular pressure applying surfaces surfaces 36 and 39 and block 32 substantially perpendicular pressure applying surfaces 37 and 40 which will be described below.

Pubic tubercle contact block 33 is bolted to the hip tracker frame 30 via bolt 122 passing through the central slot 110 and threading into the block 33 such that the user can move the contact block 33 proximally or distally to lie over the patient's pubic tubercle and then fix it rigidly to frame 30 by tightening the bolt 122

Pubic arch contact rod 34 is bolted to the hip tracker frame 30 via bolts 124 and 126 passing through the slot 112 (in the illustrated version, but could be positioned on the opposite side and the bolts 122 and 124 fed through the slot 108) and engaged in threaded connection with the mounting plate 128 fixed at one end of he rod 34 such that the rod 34 can be adjusted proximally or distally as required to contact the right inferior pubic ramus and then fixed rigidly to frame 30 by tightening the bolts 124 and 126.

Pubic arch contact rod 34 is oriented such that in the pubic arch region of the typical patient its cylindrical axis lies approximately perpendicular to the axis of the right inferior pubic ramus.

In the illustrated arrangement the strap 27 is connected at its opposite ends to the frame 30 as indicated by the belt passing through the slots 130 and 132 respectively. The strap 28 is connected at one end to the free end of the rod 34 remote from the plate 128 and at its other end to the strap 27 in a position to apply the required forces to the rod 34 in the required direction.

Marker array 35 for locating the hip tracker 26 in space (for example by mechanical, optical, optoelectronic, or electromagnetic means) is rigidly attached to the hip tracker frame 30. The attachment means may incoporate features that allow the marker array 35 to be removed and reattached in the same position relative to hip tracker frame 30 with high precision for example iteh illustrated arrangement the shaft 134 of the array is threaded into the hole 136 in the frame 30..

Crotch strap 28 is shown with buckle/adjuster 24 fastened, and waist strap 27 is shown with buckle/adjuster 29 released.

Fig. 4 is a view on the frontal plane of a typical person's pelvic region with the preferred embodiment of the hip tracker 26 applied. The outline of the patient's pelvis is shown in dashed lines (lying underneath the skin and soft tissues).

Fig. 5 is a modified section view taken from Fig. 4, looking proximally through the pelvic region of the patient with the hip tracker applied. The posterior component 41 of the total seating force applied by straps 27 and 28 is reacted by three contact forces acting anteriorly, all approximately normal to the frontal plane of the patient, as follows:

1. One contact force at surface 36 of left ASIS contact block 31 which is directed anteriorly and is substantially normal to the underlying bony structure of the left ASIS 21,

2. A second contact force at surface 37 of right ASIS contact block 32 which is directed anteriorly and is substantially normal to the underlying bony structure of the right ASIS 22, and

3. A third contact force at surface 38 of pubic tubercle contact block 33 which is directed anteriorly and is substantially normal to the underlying bony structure of the pubic tubercle 23.

These three reaction forces at contact surfaces 36, 37, and 38 are not coplanar because the pubic tubercle 23 is distal to the line between the left ASIS 21 and right ASIS 22 in normal anatomy. These three contact points therefore define the plane [in which the hip tracker lies relative to the patient and prevent orientation changes of the hip tracker relative to the patient, to the degree that the contact surface materials and the soft tissues lying over the left ASIS 21, the right ASIS 22, and the pubic tubercle 23 are incompressible. Note that in

normal anatomy the pubic tubercle 23 is distal to the line between the left ASIS 21 and right ASIS 22, therefore the contact points at surfaces 36, 37, and 38 do not lie on the same line and thus define a substantially frontal plane. Note also that contact surfaces 36, 37, and 38 could be made of compliant materials (such as rubber or gel padding) to improve comfort, at the cost of reduced effectiveness when the net posterior acting seating forces vary or move during use. Note also that the posterior component 41 of the seating forces must pass through the area bounded by the three contact points at surfaces 36, 37, and 38 in order to maintain contact and reaction forces at all three points and thereby constrain the hip tracker to a plane.

Left ASIS contact block 31 also incorporates left ASIS lateral contact surface 39, which is planar and adducted approximately 20° relative to the sagittal plane and approximately parallel to the AP direction. The reaction force at contact surface 39 due to proximal and rightward seating force components has substantial leftward and distal components.

As is known it is essential for achieving full constraint that no two contact normals be collinear and that the set of six contact normals be so arranged that it is impossible to draw a single line which intersects all of them.

Right ASIS contact block 32 also incorporates right ASIS lateral contact surface 40 and is the mirror image of left ASIS contact block 31 about the sagittal plane. The reaction force at contact surface 40 due to the proximal seating force component has substantial rightward and distal components.

Pubic arch contact rod 34 is shown passing through the right side of the crotch, contacting the patient at the skin surface over the right inferior pubic ramus 25. This contact arrangement at the pubic arch may offer improved accuracy in procedures where the left leg is manipulated. Note that pubic arch contact can be mirrored about the sagittal plane and applied to the left side instead (with a corresponding change in the seating forces from rightward to leftward) if desired.

The plane defined by contact at surfaces 36, 37, and 38 will be referred to as the frontal plane in the remaining description of this embodiment.

Fig. 6 shows a frontal view on the patient showing the bony outline of the pelvis, reaction forces with substantial components in the frontal plane, the lines of action of these reaction forces, and their corresponding contact surfaces on the hip tracker 26. The outline of the hip

tracker 26 is shown in phantom lines. This view is provided to more clearly illustrate the forces constraining the hip tracker 26 in the frontal plane (as defined by the frontal plane contact surfaces described in Fig. 5).

The proximal component of the seating forces 42 is reacted by the distal components of the reaction forces 44 and 45 acting on surfaces 39 and 40 and the distal component of reaction force 46 acting on pubic arch contact rod 34, preventing proximal-distal translation of the hip tracker 26 relative to the patient.

The opposing laterally directed components of reaction forces 44 and 45 (generated by the proximal seating force 42 and the adducted angles of contact surfaces 39 and 40) define the right-left position and prevent right-left translation of the hip tracker 26.

Due to the lack of constraint tangent to the underlying bone and the contact surfaces 39 and 40 (caused by sliding of skin over bone), the hip tracker 26 can rotate in the frontal plane about pivot point 50, which is the intersection of the lines of action of forces 44 and 45. The rightward component 43 of the seating force applied to the pubic arch contact rod 34 applies a clockwise moment to the hip tracker 26 when looking on the frontal aspect of the patient, generating reaction force 46 normal to the right inferior pubic ramus 25 where it contacts pubic arch contact rod 34. Rotation of the hip tracker 26 about pivot point 50 is prevented by the moment arm distance 47 between the line of action of reaction force 46 and pivot point 50. Similarly rotation about pivot point 51 is prevented by moment arm 48, and rotation about pivot point 52 is prevented by moment arm 49. Note that rotation of the hip tracker 26 in the frontal plane is not prevented if reaction force components 44, 45, and 46 all intersect at a common point, and that maximization of moment arm distances 47, 48, and 49 on the typical patient is critical to a successful embodiment. To prevent rotation of the hip tracker, the minimum length of distances 47, 48 and 49 must be such that the torques resisting rotation (computed as sums of cross products between relevant moment arms and reaction force vectors) are greater than the maximum torque expected to be applied to the object.

. YES – we may need to add to a claim during prosecution

Description of an Embodiment of the Invention as Adapted for Tracking the Head ('Head Tracker')

Fig. 7 shows the head of a typical patient with an embodiment of the invention as adapted for tracking the skull ("head tracker" 53) applied. A caudal-posterior seating force is applied through three contact blocks or elements 57, 58, and 59 fixed to the rigid element or frame 60 which is biased into position on the head via posterior head strap 55 and chin strap 56.

The frame 60 is formed with a main section 60a that is curves and extends from front to rear of the head and a curved branch section 60b that forms a Y shape with the main section and extends laterally thereof. A laterally projecting section curved 60c is rigid with the rest of the frame 60 and projects laterally from the forward end of the main section 60a

The head strap 55 passes through a slot 55a in the main section 60a and in a location adjacent the front of the frame 60 to apply a pressure rearward relative to the head. The strap 56 has one end connected to the free end of the branch 60b via slot 56a and at its opposite end to the slot 56b formed in the frame 60 adjacent to the intersection of the sections 60a and 60b.

Three contact elements 57, 58, and 59 are each bolted to the rigid element or frame 60 in the illustrated arrangement by suitable bolts 200, 202 and 204 respectively. The bolts pass through their respective slots 200a, 202a and 204a in the frame 60 and 200b, 202b and 204b the pressure element such that they can be moved to the desired position and then fixed rigidly to frame 60. This mounting system provides for adjustment in two mutually perpendicular directions and for rotation about the axis of the respective bolts.

The slots 200a and 204a are provided in the main section 60a and the slot 202a in the branch section 60b so three contact elements 57, 58, and 59 may contact an approximately spherical portion of the skull such that the lines of action of each of the three reaction forces normal to the skull are substantially non-collinear. In this example, they will approximately intersect at the nominal centre point of the spherical portion of the skull.

It is permissible to have three lines of action intersect, as long as none of the three remaining normal constraints intersect the common point of these first three. The first three need not intersect, but such an arrangement often makes it easier for the designer to visualize how to complete the design, although there is no fundamental reason why they must.

A fourth contact element 61 (zygomatic arch contact element 61) is mounted adjacent to a free end of section 60c via a bolt 206 passing through slot 206a in the frame 60 and 206b in the element 62 to permit the same types of relative adjustment between the frame 60 and element 61 as can be attained with the other elements 57, 58 and 59. The fourth element 61 forms a fourth constraint applied by zygomatic arch contact element 61 with a line of action normal to the underlying bone of the zygomatic arch which will not pass through the spherical centre defined by the intersection of the lines of action normal to the skull at the three contact elements 57, 58, and 59.

Nasal bone contact element 62 is mounted on the forward part of the frame section 60a (forward of the slot 55a via a bolt 208 passing through slot 208a in the frame 60 and 208b in the element 62 to permit the same types of relative adjustment between the frame 60 and element 62 as can be attained with the other elements 57, 58 and 59. The fifth element 62 provides the fifth and sixth constraints by contacting the skin over the left and right nasal bones via cylindrical shaped contact pads 62a and 62b (see Figure 8). In normal anatomy, the lines of action normal to the two nasal bones passing through the contact points will intersect at a pivot point located in the nasal passage, a substantial distance from a spherical centre defined by the intersection of the three lines of action normal to the skull passing through the three contact points 57, 58, and 59.

Note that if contact elements 57, 58, and 59 contact a spherical portion of the skull such that the lines of action of each of the three reaction forces normal to the skull substantially intersect at a common point, the head tracker 53 can rotate relative to the head about the line passing through this common point perpendicular to the plane of the reaction forces at nasal bone contact element 62. Therefore there must be a substantial perpendicular distance between the line of action of the reaction force at zygomatic arch contact element 61 and this line. In detail design of the head tracker 53, this perpendicular distance is maximized for typical patient anatomy and normally will exceed 2 cm.

Marker array 54 for locating the head tracker 53 in space (for example by mechanical, optical, optoelectronic, or electromagnetic means) is rigidly attached to the head tracker frame 60 by any suitable means. The attachment means may incoporate features that allow the marker array 54 to be removed and reattached in the same position relative to head tracker frame 60 with high precision.

Fig. 8 is a view looking crainially and posteriorly, parallel to the bridge of the nose, showing the contact point between the patient and the zygomatic arch contact element 61 and the two contact points at nasal bone contact with pads 62a and 62b of element 62. The two cylindrical surfaces of nasal bone contact pads 62a and 62b of element 62 give point contact to a variety of included angles between the nasal bones ('flat' or 'sharp' noses).

Description of an Alternate Embodiment of the Invention as Adapted for Tracking the Pelvis ('Hip Tracker')

This additional embodiment of the invention as adapted for tracking the pelvis is described to illustrate that different arrangements of constraints can be used for a particular bony structure. These different arrangements may be desirable to maximize constraint, avoid particular contact points, allow access to certain areas of the patient, or other design or utility reasons.

Fig. 9 is a view looking posteriorly on the frontal aspect of the patient's pelvic region with the alternate embodiment of the hip tracker 92 applied. Seating forces are applied by waist strap 96 and crotch strap 97 (see Fig. 10) and act in a posterior, proximal, and leftward direction.

Fig. 10 is a modified sectional view taken on line 10 10 of Fig. 9, looking proximally through the pelvic region of the patient with the alternate embodiment of the hip tracker applied. Similarly to the preferred embodiment (Figure 3), the construction is essentially the same and uses slots, bolts in the rigid frame member 300 to secure the various blocks equivalent to blocks 30, 31 and 32 namely blocks 75, 76 and 33 respectively to the frame 300.

In the figure 9 and 10 embodiment the posterior component 80 of the total seating force is reacted by three contact forces acting anteriorly, all approximately normal to the frontal plane of the patient, at surfaces 93, 94, and 95 on the soft tissue over left ASIS 21, right ASIS 22, and pubic tubercle 23. These three contact points define the plane in which the hip tracker 92 lies relative to the patient and prevent orientation changes of the hip tracker relative to the patient, to the degree that the contact surface materials and the soft tissue lying over the bone at the contact points are incompressible.

In contrast to the preferred embodiment, note that alternate strap 96 (connected at opposite ends to the frame member 300) applies a posterior, proximal leftward seating force and crotch strap 97 applies a substantially posterior and proximal seating force to the hip tracker.

Alternate left ASIS contact block 75 does not have a lateral contact surface, and generates no substantial reaction forces not perpendicular to the frontal plane.

Alternate right ASIS contact block 76 also incorporates right ASIS lateral contact surface 79 which is substantially parallel to the sagittal plane. The reaction force at right ASIS lateral contact surface 79 has a substantial rightward component but no substantial distal component.

Pubic arch contact element 77 is different from that of Figure 3 and is in effect U shaped with opposite ends bolted to the frame 300 in a similar manner to the manner in which the plate 128 is fixed to the frame 30. The element 77 passes through the right and left sides of the crotch, contacting the patient at the skin surface over the right inferior pubic ramus 25 and left inferior pubic ramus 78.

The plane defined by contact at surfaces 93, 94, and 95 will be referred to as the frontal plane in the remaining description of this embodiment.

Fig. 11 shows a frontal view on the patient showing the bony outline of the pelvis, reaction forces with substantial components in the frontal plane, the lines of action of these reaction forces, and their corresponding contact surfaces on the hip tracker 92. The outline of the hip tracker 92 is shown in phantom lines. This view is provided to more clearly illustrate the forces constraining the hip tracker 92 in the frontal plane (as defined by the frontal plane contact surfaces described in Fig. 10).

The proximal component of the seating forces 81 is reacted by the distal components of the reaction forces 84 and 85 acting on pubic arch contact element 77 preventing proximal-distal translation of the hip tracker 92 relative to the patient. The opposing medially directed components of reaction forces 84 and 85 (generated by the proximal seating force 81 and the angles of the pubic arch) define the right-left position and prevent right-left translation of the hip tracker 92.

The leftward component 82 of the seating forces applies a leftward force to the hip tracker 92 when looking on the frontal aspect of the patient, generating reaction force 83 normal to

the right ASIS lateral contact surface 79 and a portion of the leftward component of left pubic arch reaction force 84.

Due to the lack of constraint tangent to the underlying bone and the two pubic arch contact points (caused by sliding of skin over bone), the hip tracker 92 can rotate in the frontal plane about pivot point 89, which is the intersection of the lines of action of forces 84 and 85. The leftward component 82 of the seating forces applies a clockwise moment to the hip tracker 92 about pivot point 89 when looking on the frontal aspect of the patient, reacted primarily by right ASIS lateral reaction force 83.

Rotation of the hip tracker 92 about pivot point 89 is prevented by the moment arm distance 86 between the line of action of reaction force 83 and pivot point 89. Similarly rotation about pivot point 90 is prevented by moment arm 87, and rotation about pivot point 91 is prevented by moment arm 88. . To prevent rotation of the hip tracker 92, the minimum length of distances 86, 87 and 88 must be such that the torques resisting rotation (computed as sums of cross products between relevant moment arms and reaction force vectors) are greater than the maximum torque expected to be applied to the object. In practice the minimum length of the moment arms 86, 87 or 88 will not be less than 5 cm.

Operation of the Preferred Embodiment of the Inventions

Operation of the Preferred Embodiment of the Invention as Adapted for Tracking the Pelvis ('Hip Tracker')

To use the preferred embodiment of the hip tracker 26 as shown in **Fig. 1(b)**, locate the left anterior superior iliac spine (ASIS) 21, the right ASIS 22, and the pubic tubercle 23 of the patient as shown in **Fig. 1(a)**. Referring to **Fig. 3**, adjust left ASIS contact block 31 and right ASIS contact block 32 to the right or left in the slots incorporated in hip tracker frame 30 such that they contact the skin over the most prominent portion of the left ASIS 21 and right ASIS 22, maintaining the centreline of the pubic tubercle contact block 33 approximately at the midline of the patient. Tighten the bolts to fix blocks 31 and 32 rigidly to frame 30. Adjust the pubic tubercle contact block 33 proximally or distally to contact the skin over the pubic tubercle 23 and tighten the bolt to fix contact block 33 rigidly to frame 30.

If applicable, select which side of the pubic arch to contact for best accuracy, usually the side opposite the leg that must be moved during the position recording procedure. The right side is used in this description. Slide pubic arch contact rod 34 proximally until it contacts the skin over the inferior pubic ramus 25 (shown in **Fig. 5**) and fix rigidly to frame 30.

Pass waist strap 27 around the patient's waist proximal to the posterior superior iliac spines, adjust the length of waist strap 27 using adjuster/buckle 29 such that when adjuster/buckle 29 is fastened, waist strap 27 is under tension sufficient to maintain firm contact at points 21, 22, and 23 (see **Fig. 1a**) under the expected forces and movements during the position recording procedure. Referring to **Fig. 2**, ensure that waist strap 27 passes around the waist high enough to pull the hip tracker 26 proximally on the patient. Referring to **Fig. 4** and **Fig. 5**, left ASIS contact block 31 lateral contact surface 39 and right ASIS contact block 32 lateral contact surface 40 must both firmly contact the patient's skin over the left ASIS 21 and right ASIS 22 respectively as a result of the proximal pull from waist strap 27.

Referring to **Fig. 2**, ensure that crotch strap 28 attaches to waist strap 27 on the same side of the patient as the side of the pubic arch chosen for contact to pubic arch contact rod 34 (in the illustration the right side) and adjust the length of crotch strap 28 using adjuster/buckle 24 such that when adjuster/buckle 24 is fastened, crotch strap 28 is under tension sufficient to maintain firm contact at the right inferior pubic ramus 25 (see **Fig. 5**) under the expected forces and movements during the position recording procedure.

Note that once contact blocks 31, 32, and 33 and pubic arch contact rod 34 are adjusted and fixed to frame 30, the hip tracker 26 can be removed and if no subsequent adjustments are made, hip tracker 26 can be reinstalled on the patient in substantially the same position by reapplying straps 27 and 28 (or providing similar seating forces, for example holding the tracker to the patient) and ensuring that firm contact is made at all six contact points between the patient's skin and contact surfaces 36, 37, 38, 39, and 40 as well as pubic arch contact rod 34.

Operation of an Embodiment of the Invention as Adapted for Tracking the Head ('Head Tracker')

Referring to **Fig. 7**, adjust three contact elements 57, 58, and 59 on frame 60 to the desired positions on the skull and then fix rigidly to frame 60. Adjust nasal bone contact element 62 to contact the skin over the left and right nasal bones (as shown in **Fig. 8**) and fix rigidly to

frame 60. Adjust zygomatic arch contact element 61 on frame 60 such that it contacts the skin over the zygomatic arch (as shown in **Fig. 8**) and fix rigidly to frame 60.

Arrange and adjust the lengths of posterior head strap 55 and chin strap 56 as shown in **Fig. 7** to maintain firm contact at contact elements 57, 58, and 59, nasal bone contact element 62, and zygomatic arch contact element 61 under the expected forces and movements during the position recording procedure.

Note that once contact elements 57, 58, and 59, nasal bone contact element 62, and zygomatic arch contact element 61 are adjusted and fixed to frame 60, the head tracker 53 can be removed and if no subsequent adjustments are made, head tracker 53 can be reinstalled on the patient in substantially the same position by reapplying straps 55 and 56 (or providing similar seating forces, for example holding the tracker to the head) and ensuring that firm contact is made at all six contact points between the patient's skin and elements 57, 58, and 59, nasal bone contact element 62, and zygomatic arch contact element 61.

Operation of an Alternate Embodiment of the Invention as Adapted for Tracking the Pelvis ('Hip Tracker')

Operation of the alternate embodiment of the hip tracker 92 is similar to that of the preferred embodiment of the hip tracker 26 (described above) except as follows:

Referring to **Fig. 9** and **Fig. 10**, adjust left ASIS contact block 75, right ASIS contact block 76, and pubic tubercle contact block 33 such that frontal plane contact surfaces 93, 94, and 95 contact the skin over the most prominent portion of the left ASIS 21, right ASIS 22, and pubic tubercle 23 (shown in **Fig 1a**).

Slide pubic arch contact element 77 proximally until it contacts the skin over the left inferior pubic ramus 78 and the right inferior pubic ramus 25 (shown in **Fig. 10**).

Adjust and fasten waist strap 96 around the patient's waist proximal to the posterior superior iliac spines. Ensure that tension in waist strap 96 is sufficient to generate sufficient leftward pull on the hip tracker 92 to maintain firm contact at right ASIS lateral contact surface 83 (see **Fig. 10**), and sufficient posterior pull to maintain firm contact at left ASIS frontal plane contact surface 93, right ASIS frontal plane contact surface 94, and pubic tubercle frontal

plane contact surface 95 (see **Fig. 10**) under the expected forces and movements during the position recording procedure.

Ensure that crotch strap 97 attaches to waist strap 96 roughly at the midline of the patient such that when adjusted and fastened under tension, crotch strap 97 maintains a proximal pull on the hip tracker 92 sufficient to maintain firm contact betwenn pubic arch contact element 77 and the skin over the right inferior pubic ramus 25 and the left inferior pubic ramus 78 (see **Fig. 10**) under the expected forces and movements during the position recording procedure.

A special version of the contacting block surfaces is shown in Figure 12 In this version the contact block 500 has a pressure contacting surface 502, which could be any of the contacting surfaces described for the various embodiments of the invention shown in the other drawings, and which incorporates an ultrasound transducer 504 that delivers a signal to the signal processor 506 as indicated by the line 508. The signal processor 506 determines the distance between the contact surface 502 and the bone (not shown) against which it presses based on the signal from the transducer 504. This information may be used in any suitable manner. For example, it could be delivered as schematically indicated by the line 510 to a warning or display device 512 that may show the actual or the change in spacing and/or send a warning if the distance between any one of the contacting surfaces 502 and the bone exceeds a preset limit.

It will be apparent to one skilled in the art that variations of this method in which additional normal constraints are applied through adjustable means may effectively convert a force-closed constraint to a form-closed constraint which may in selected cases improve the resistance of the system to dislodgement without affecting the degree of relative movement or repeatability during remounting.

It will also be apparent to one skilled in the art that the comparatively rigid constraints described in this method may be replaced with compliant elements, which will degrade the localizing accuracy and remounting repeatability in proportion to the degree of compliance of said elements. In particular applications, the maximum accuracy possible through the use of rigid contact elements may not be strictly required, but it will be clear that the selection of a contact element that is rigid enough for the demands of the application remains within the spirit of this invention.

It will also be apparent to one skilled in the art that comparatively non-compliant elements such as straps may be used to apply seating forces in cases where the expected loads on the external object relative to the bony structure are not expected to vary significantly.

CLAIMS

1. A device for indicating the position of a rigid body covered with a layer of soft pliable material, comprising: a rigid element, a plurality of contact surfaces mounted on said rigid element, said contact surfaces being arranged in a pattern wherein each said surface is oriented at a different angle to a reference line of said rigid element so that when the surfaces contact the soft material said contact surfaces apply pressure in different directions relative to said reference line and in a direction normal to an underlying portion of said rigid body, thereby to fix said rigid element substantially immobile relative to said rigid body by a reaction force at each of said contact surfaces acting on said rigid body through said layer of soft pliable material, and a seating means of applying a seating force between said rigid element and said rigid body to force said contact surfaces to apply said pressure and maintained said pressure at each said contact surface during use of the device whereby relative motion between said rigid element and said rigid body due to the soft pliable material sliding tangentially over the body is minimised.

2. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in claim 1 wherein said plurality of contact surfaces comprises 6 contact surfaces.

3. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in claim 1 or 2 wherein at least one of the contact surfaces is adjustable in position relative to said rigid element to accommodate a range of sizes and shapes of said rigid body.

4. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in any one of the preceding claims wherein at least one of the contact surfaces is covered with padding material to prevent damage of said layer of soft material.

5. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in any one of the preceding claims wherein a marker array is fixed to said rigid element.

6. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in any one of the preceding claims wherein at least one of

said contacting surfaces incorporates means of measuring thickness of said layer of soft material at said at least one contact surface and means of determining the change in said thickness.

7. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in any one of the preceding claims wherein each of said contact surfaces incorporates means of measuring thickness of said layer of soft material at its said contact surface and means of determining the change in said thickness at each said contact surface.

8. A device for indicating the position of a rigid body covered with a layer of soft pliable material as defined in claim 6 or 7 wherein said means for measuring thickness comprise ultrasonic means.

9. A method of indicating the position of a rigid body when said rigid body is covered with a layer of soft material, comprising the steps of arranging six contact surfaces and fixing them to a common rigid frame applying said rigid frame so that said surfaces contact the soft material and fully constrain said rigid frame relative to said rigid body by a reaction force at each of the contact surfaces, acting through said layer of soft material substantially normal to the surface of said rigid body in the region of contact, and applying a seating force between said rigid frame and said rigid body such that a reaction force is maintained at each contact surface during use.

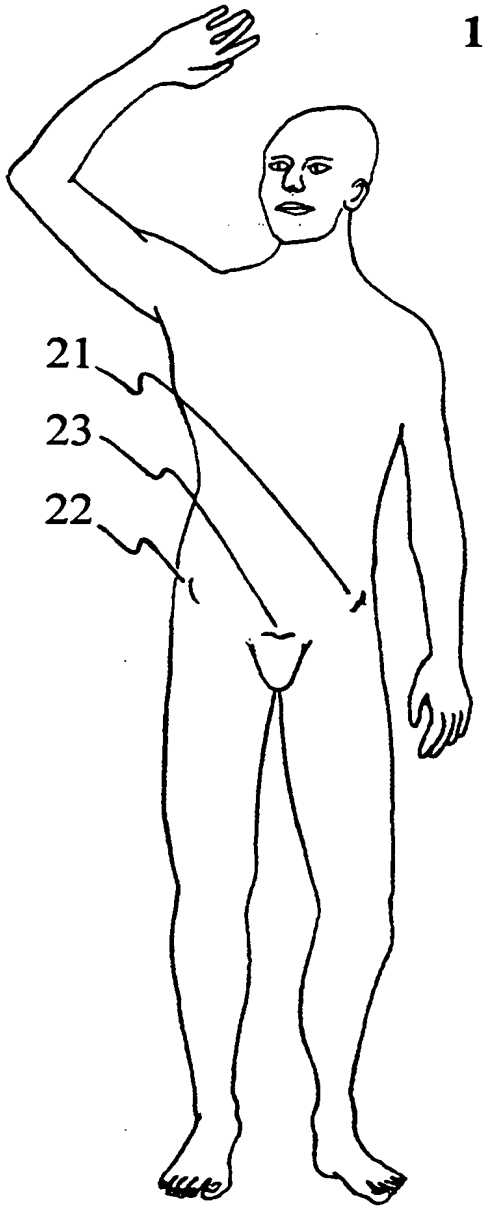

Fig. 1(a)

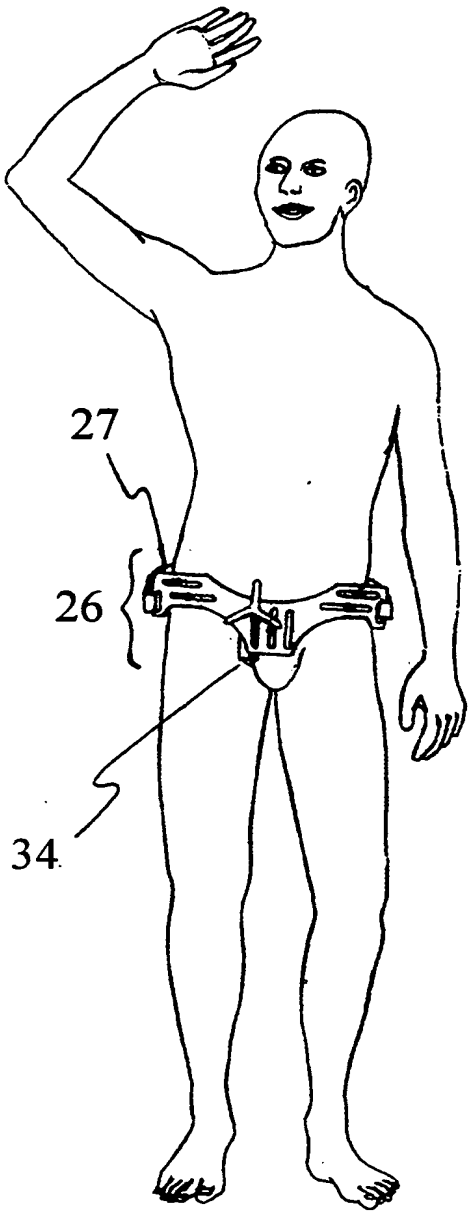

Fig. 1(b)

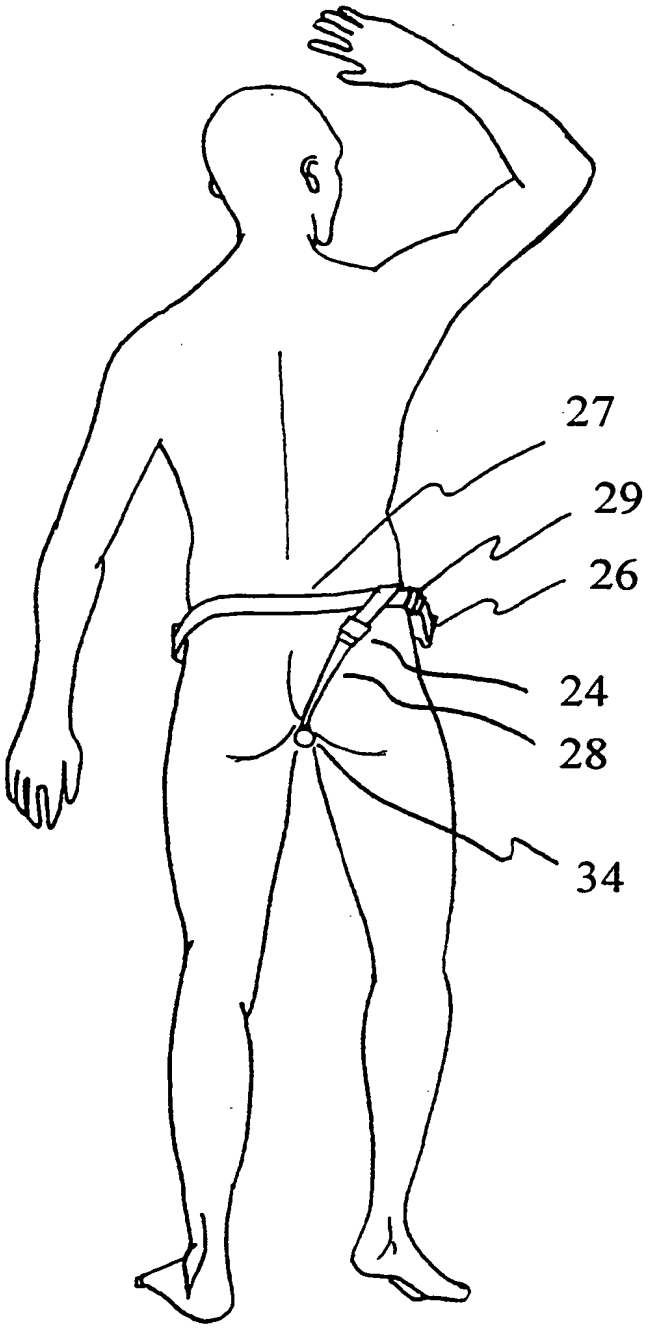

Fig. 2

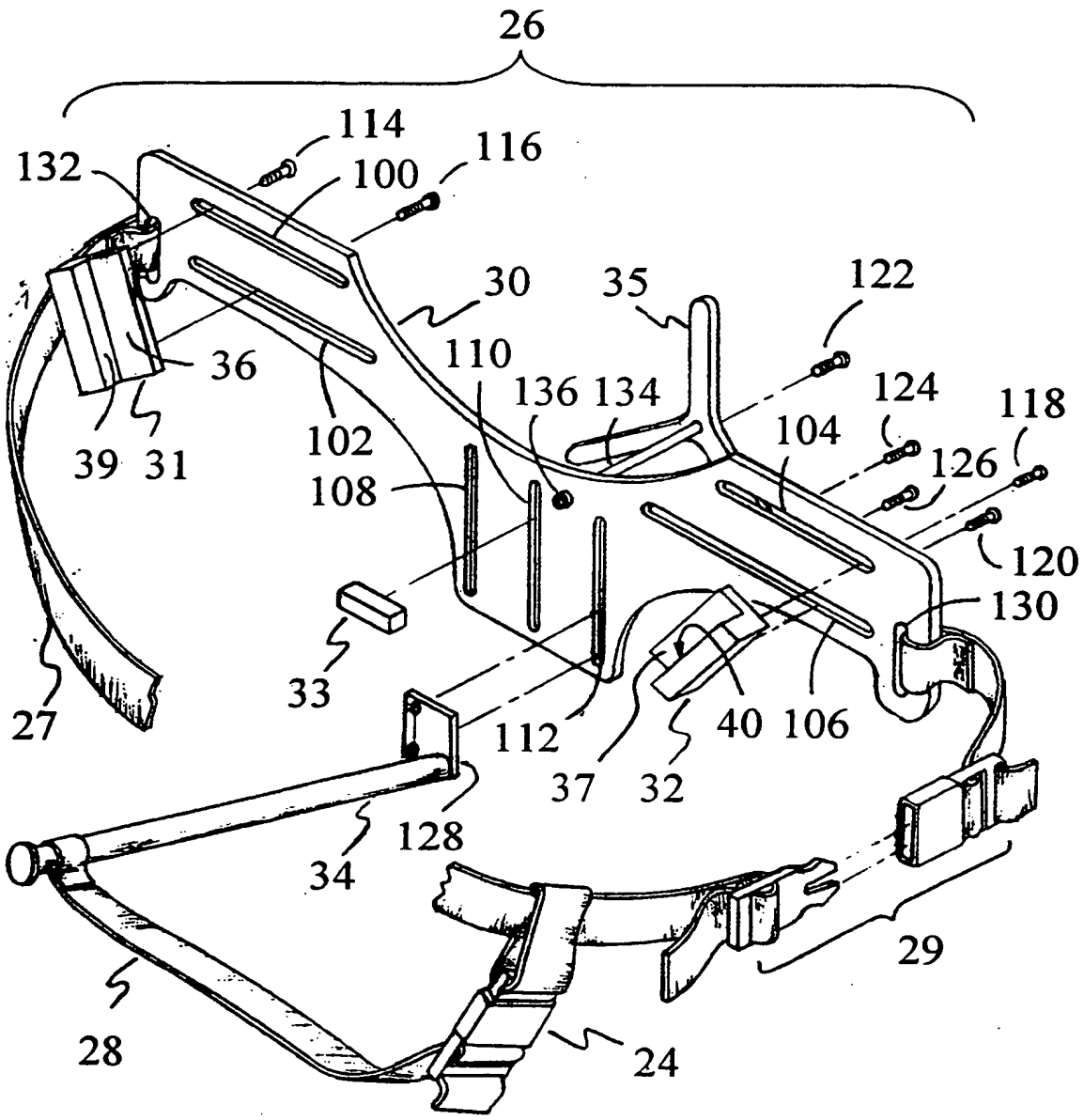
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Fig. 3

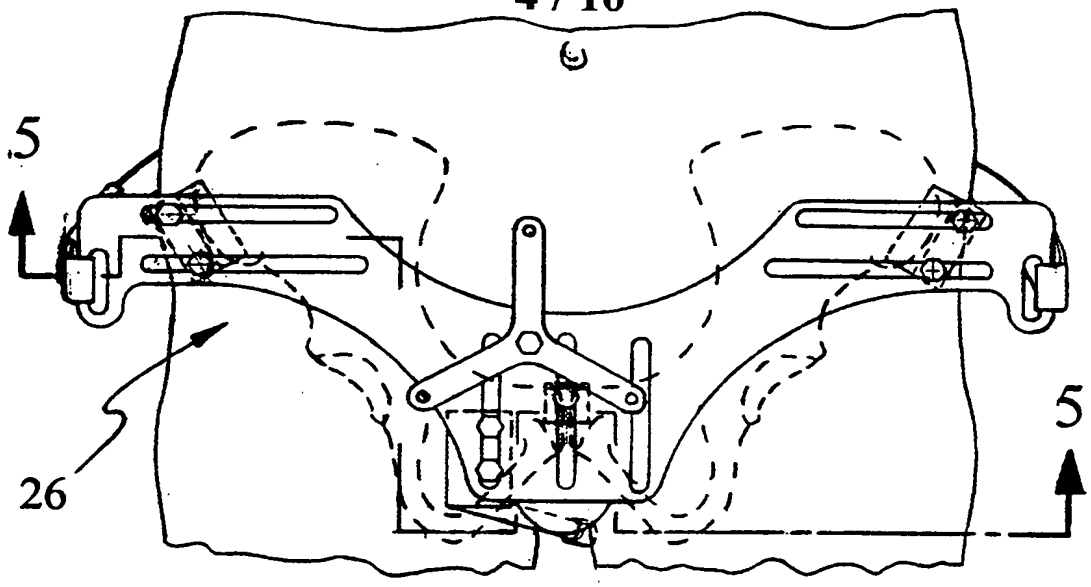

Fig. 4

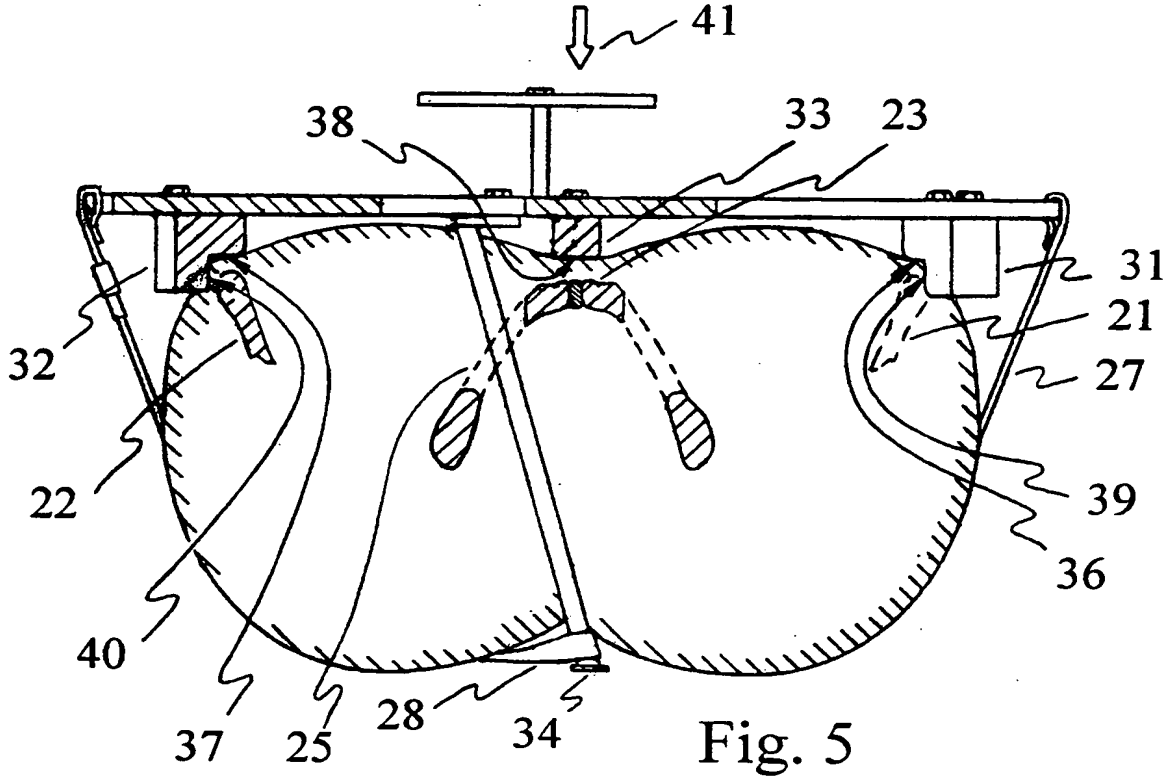

Fig. 5

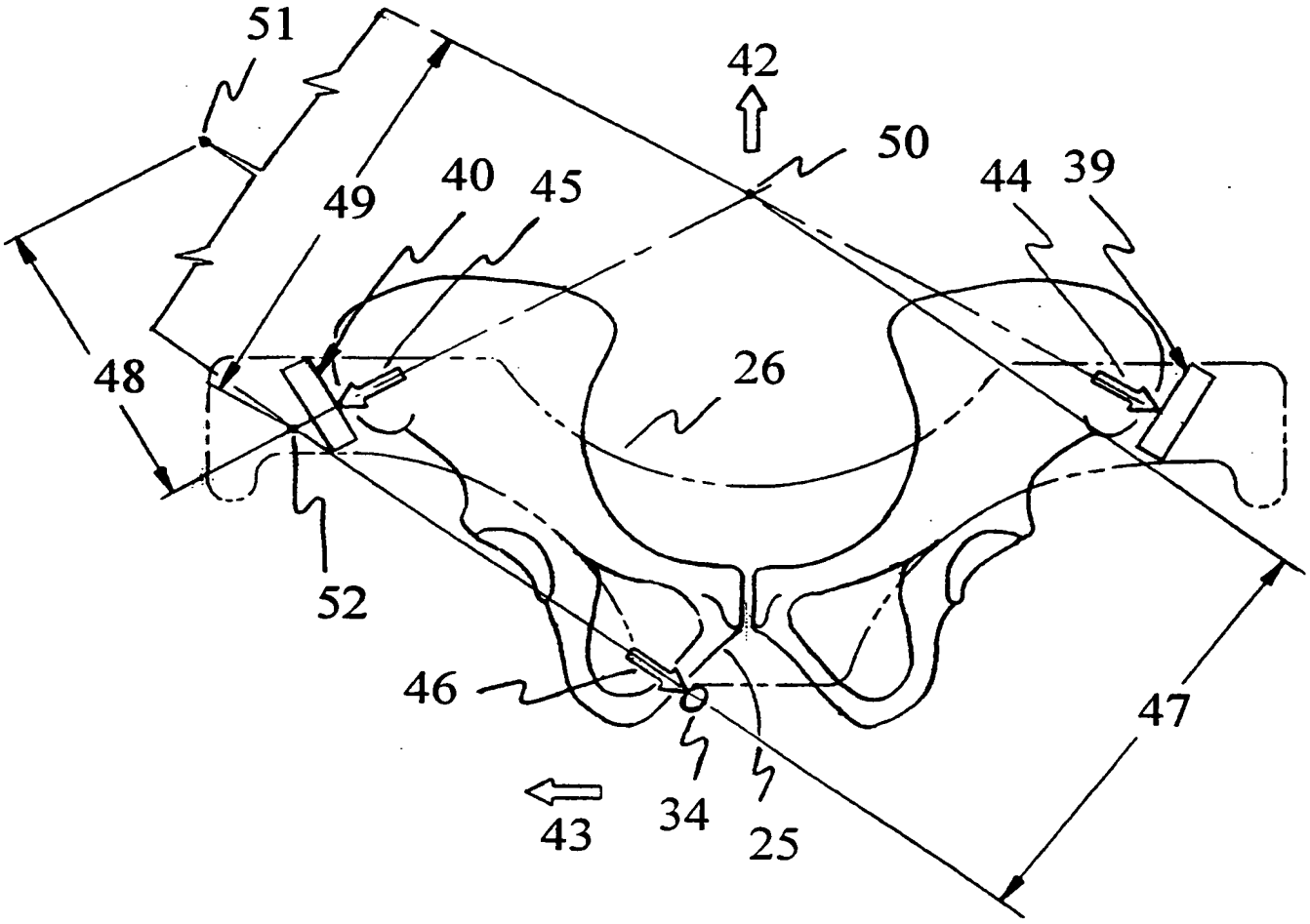

Fig. 6

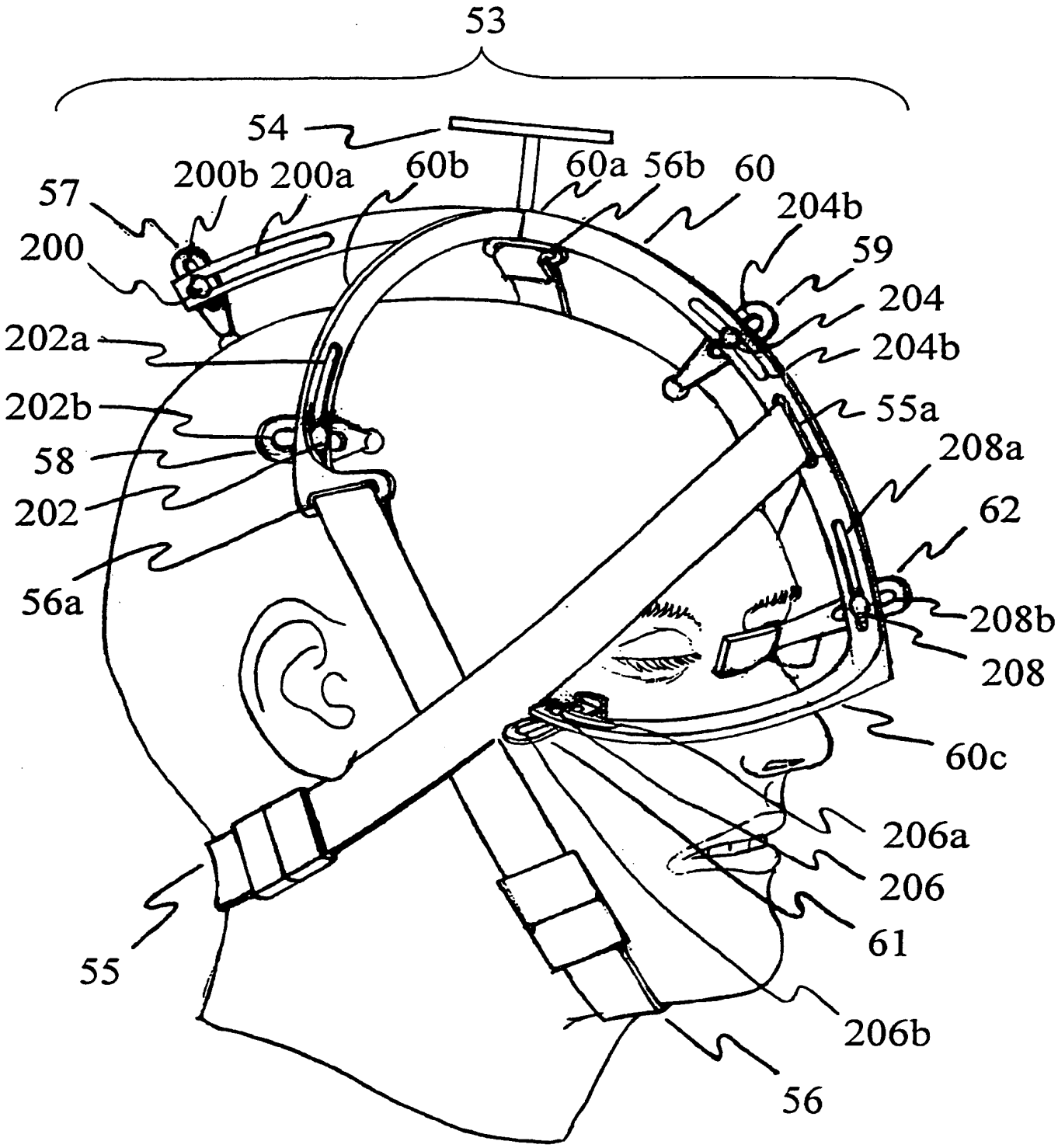
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Fig. 7

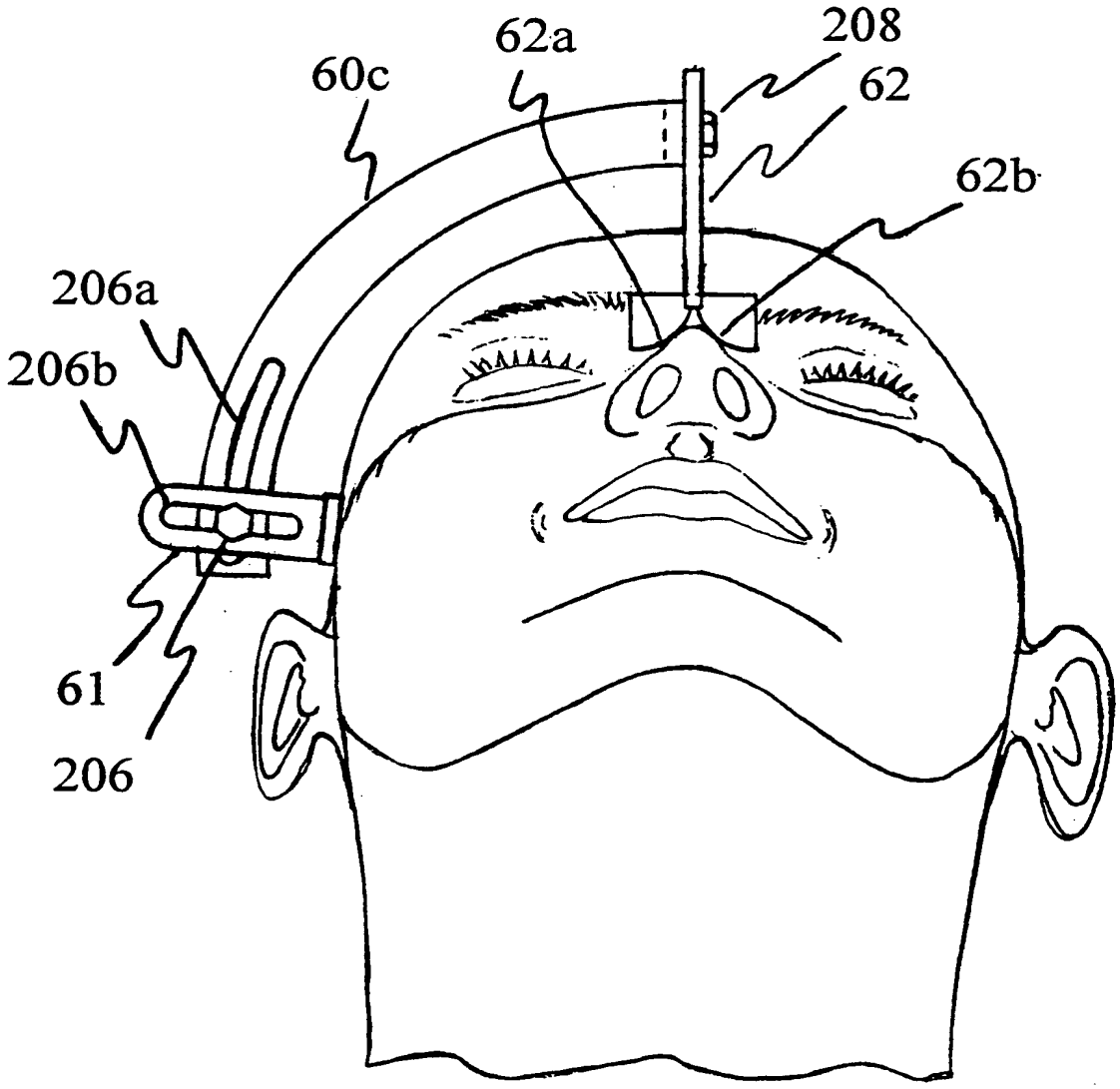

Fig. 8

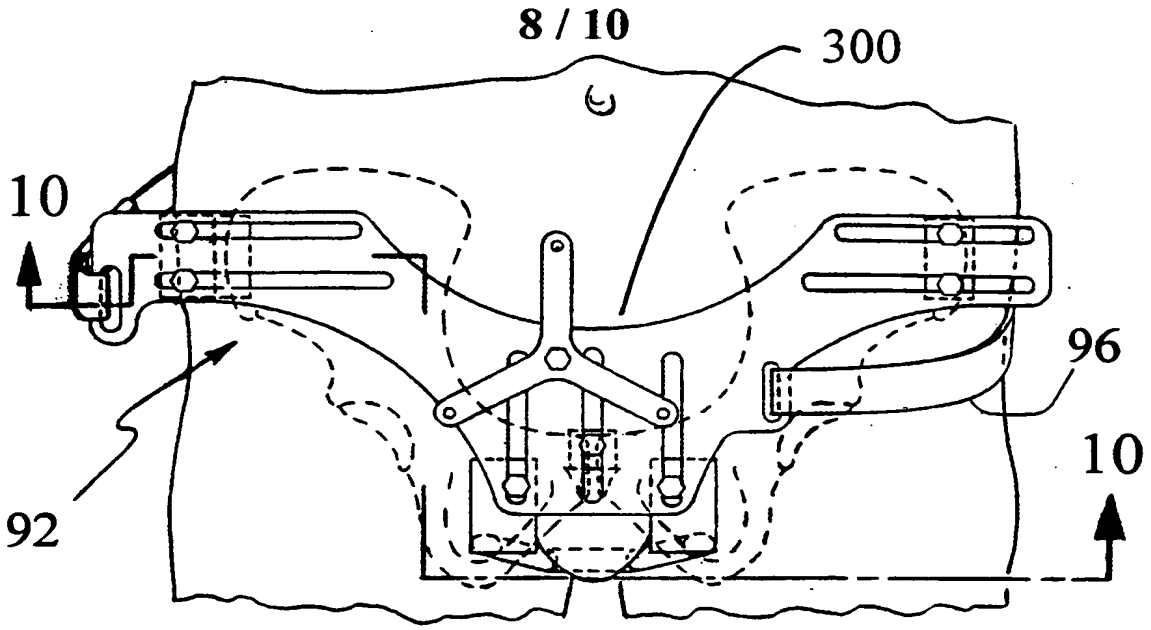

Fig. 9

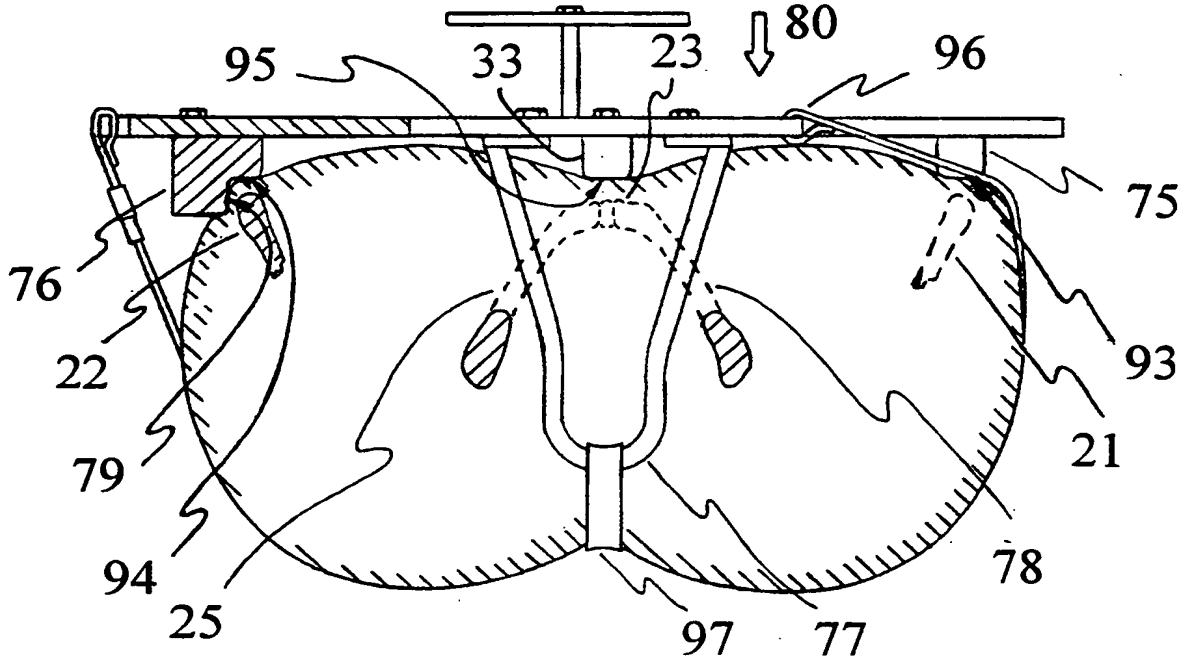

Fig. 10

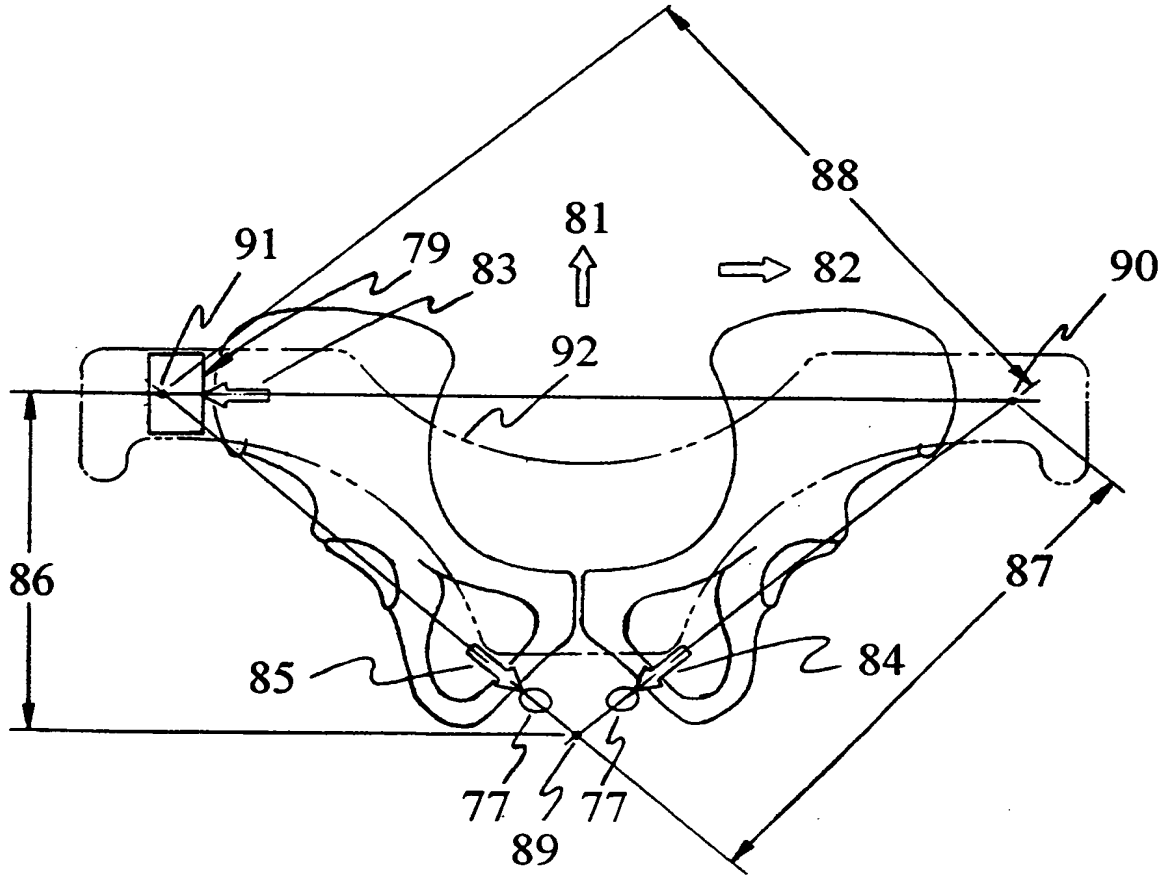

Fig. 11

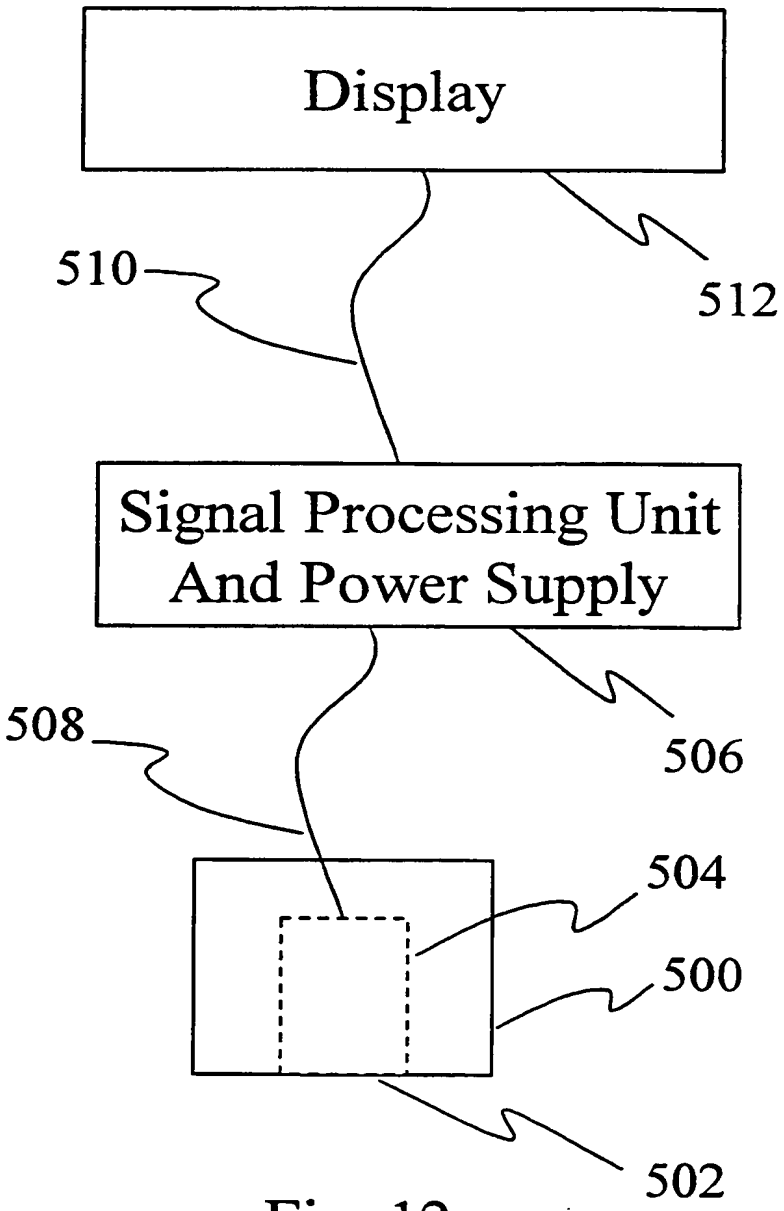
Display
510
512
Signal Processing Unit
And Power Supply
508
506
504
500
502

Fig. 12

INTERNATIONAL SEARCH REPORT

Intern. ıal Application No
PCT/CA 00/01071

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 423 832 A (GILDENBERG PHILIP L) 13 June 1995 (1995-06-13)	1,3-5
A	column 10, line 56 -column 11, line 6; figures 8,9	2,6,7,9
X	US 5 601 569 A (PISHARODI MADHAVAN) 11 February 1997 (1997-02-11) cited in the application	1,3-5
A	column 3, line 24 - line 38; figure 1	9
X	DE 43 42 971 C (KOCH AXEL DR DR MED) 23 March 1995 (1995-03-23)	1,3-5
A	column 4, line 46 - line 60; figure 1	9
A	FR 2 627 978 A (CESSOT CHRISTIAN) 8 September 1989 (1989-09-08) abstract	6-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 December 2000	20/12/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mayer, E

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern. .al Application No
PCT/CA 00/01071

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5423832 A	13-06-1995	NONE	
US 5601569 A	11-02-1997	US 5387220 A	07-02-1995
		AU 7058094 A	03-01-1995
		CA 2167297 A	22-12-1994
		EP 0703759 A	03-04-1996
		WO 9428819 A	22-12-1994
DE 4342971 C	23-03-1995	NONE	
FR 2627978 A	08-09-1989	AT 107149 T	15-07-1994
		DE 68916239 D	21-07-1994
		EP 0407409 A	16-01-1991
		WO 8907910 A	08-09-1989

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

12

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
UBC135PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA00/01071	15/09/2000	17/09/1999
International Patent Classification (IPC) or national classification and IPC A61B19/00		
Applicant THE UNIVERSITY OF BRITISH COLUMBIA et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17/04/2001	13.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Vänttinen, H Telephone No. +49 89 2399 7442

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/01071

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-22 as originally filed

Claims, No.:

1-9 as originally filed

Drawings, sheets:

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2,6-9
	No:	Claims	1,3-5
Inventive step (IS)	Yes:	Claims	6-9
	No:	Claims	1-5
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations
   see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

1 Concerning Item V

1.1 The subject-matter of claim 1 has been defined using such general and abstract terms that the device disclosed by US-A-5 423 832 (D1) falls under the wording of claim 1. D1 discloses a device for indicating the position of a rigid body (the skull) covered with a layer of soft pliable material (the scalp), the device comprising a rigid element (76), a plurality of contact surfaces (118) mounted on said rigid element as claimed and seating means (84, 94, 100) as claimed. Also US-A-5 601 569 (D2) and DE-C-43 42 971 (D3) are considered to disclose devices which fall under the wording of claim 1. Thus, the subject-matter of claim 1 does not meet the requirements of Article 33(2) PCT.

1.2 In addition, the dependent claims 3-5 do not appear to disclose any additional features in combination with claim 1 in order to meet the requirements of Article 33(2) PCT (see D1-D3).

1.3 The subject-matter of dependent claim 2 is considered to relate merely to one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. Thus, the subject-matter of claim 2 does not meet the requirements of Article 33(3) PCT.

1.4 The subject-matter of dependent claims 6-8 appears to meet the requirements of Article 33(2) and (3) PCT, because none of the cited documents appears to disclose the subject-matter or lead the skilled person to the subject-matter of said claims.

1.5 The independent method claim 9 is considered to meet the requirements of Article 33(2) and (3) PCT, because D1, being considered as the closest prior art, or any other cited document is not considered to teach the method steps of claim 9.

2 Concerning Item VII

2.1 To meet the requirements of Rule 5(a)(ii) PCT, at least D1 should have been identified in the description and its relevant contents should have been indicated. Consequently, the applicant should have drafted the independent claims in the two-part form in accordance with the Rule 6.3(b) PCT with those features known in

combination from D1 being placed in the preamble and with the remaining features being included in the characterizing portion.

2.2 Reference signs in parentheses should have been inserted in all the claims to increase their intelligibility, Rule 6.2(b) PCT.